Kansas Department of Health and Environment

Division of Health

Bureau of Environmental Health

REGULATORY IMPACT STATEMENT CONSISTING OF:

I. ENVIRONMENTAL BENEFIT STATEMENT

AND

II. ECONOMIC IMPACT STATEMENT

Pursuant to K.S.A. 77-416

June 22, 2010

Part 1: GENERAL
Proposed Amendment of Radiation Protection Regulations:
K.A.R. 28-35-135l, 28-35-135t and 28-35-135w

PART 3: LICENSING OF SOURCES OF RADIATION
Proposed Amendment of Radiation Protection Regulations:
K.A.R 28-35-175a, 28-35-178b, 28-35-178e, 28-35-178j, 28-35-180b, 28-35-181a, 28-35-181j, 28-35-181m, 28-35-181o, 28-35-192b, 28-35-192c, 28-35-192e, 28-35-192g, 28-35-194a
Proposed Revocation of Radiation Protection Regulations:
28-35-181e, 28-35-192d

PART 4: STANDARDS FOR PROTECTION AGAINST RADIATION
Proposed Amendment of Radiation Protection Regulations:
K.A.R. 28-35-212a, 28-35-216a, 28-35-231c
Proposed New Regulation:
K.A.R. 28-35-225a

PART 5: USE OF X-RAYS IN THE HEALING ARTS
Proposed Amendment of Radiation Protection Regulations:
K.A.R 28-35-242

PART 6: USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS
Proposed Amendment of Radiation Protection Regulations:

K.A.R 28-35-264

PART 10: NOTICE, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS
Proposed Amendment of Radiation Protection Regulations:
K.A.R. 28-35-334

PART 11: WIRELINE AND SUBSURFACE TRACER STUDIES
Proposed Amendment of Radiation Protection Regulations:
K.A.R 28-35-346

PART 13: CONTINGENCY PLANNING FOR RESPONSE TO RADIOACTIVE MATERIAL EMERGENCIES
Proposed Amendment of Radiation Protection Regulations:
K.A.R. 28-35-411

Background of Proposed Amendments

The Nuclear Energy Development and Radiation Control Act, (K.S.A. 48-1601, et seq.) requires the State to develop rules and regulations for the use of all radiation, radiation machines, and radioactive materials to ensure the maximum protection of the public health and the maximum safety to all persons at, or in the vicinity of, the place of use, storage, or disposal of sources of radiation. These regulations are intended to be consistent with the best use of radiation machines and radioactive materials, and to encourage the constructive uses of radiation.

These regulations shall apply to all persons who receive, posses, use, transfer, own or acquire any source of radiation, except as otherwise specified. The provisions of these regulations shall not limit the exposure of patients to radiation for the purpose of diagnosis or therapy, by persons licensed to practice one or more of the healing arts, dentistry or podiatry.

Under KSA 48-1601 and related statutes, the State of Kansas entered into an agreement with the Nuclear Regulatory Commission (NRC) in 1965 to regulate byproduct and certain special nuclear materials under the provisions of the federal Atomic Energy Act as amended by the Energy Policy Act of 2005. Kansas has operated as an *agreement state* since January 1, 1965. The regulated community in Kansas includes over 300 facilities licensed to use radioactive materials and 2,500 facilities registered to use x-ray equipment. These facilities include industrial operations, research labs, medical and dental facilities, and security screening operations. In order to assure appropriate protection of the public and operators, radiation exposures must be kept as low as reasonably achievable (ALARA). The role of the Radiation Control Program is to provide the appropriate oversight and regulation. K.S.A. 48-1601 requires that the state provide for compatibility with the standards and regulatory programs of the federal government.

The amendments, revocations and new regulations included in the package fall into two broad categories. The first category encompasses regulations that need to be updated to maintain compatibility with the corresponding Nuclear Regulatory Commission(NRC) regulation. The second category includes regulations that are being updated to meet internal or external stakeholder requests to clarify or improve the structure of the existing regulations. A detailed listing of each regulation follows that indicates the necessity for change.

Summary of Regulation Changes

Part 1: GENERAL

Amended regulations: K.A.R. 28-35-135l, 28-35-135t and 28-35-135w

Regulations 28-35-135l, 28-35-135t and 28-35-135w were changed to meet compatibility requirements with the NRC regulations and to correct an error. The terms impacted for NRC compatibility were Total Effective Dose Equivalent (TEDE) and Waste. The corrected definition was for the Low dose-rate remote afterloader.

PART 3: LICENSING OF SOURCES OF RADIATION

Amended regulations: K.A.R 28-35-175a, 28-35-178b, 28-35-178e, 28-35-178j, 28-35-180b, 28-35-181a, 28-35-181j, 28-35-181m, 28-35-181o, 28-35-192b, 28-35-192c, 28-35-192e, 28-35-192g, 28-35-194a

Revoked regulations: 28-35-181e, 28-35-192d

Regulation 28-35-175a was changed to clarify the requirement for licensing as it applies to persons who own or acquire radioactive material to maintain compatibility with the NRC.

Regulation 28-35-178b was changed to add requirements for the element Radium and additional requirements for transfer for specific licensees as required to maintain compatibility with the NRC.

Regulation 28-35-178e was changed to add requirements for the element Radium as required to maintain compatibility with the NRC.

Regulation 28-35-178j was changed to replace the word by-product with the word radioactive to maintain the same meaning as the NRC definition of by-product has changed. This change was required to maintain compatibility with the NRC.

Regulation 28-35-180b was changed to correct an error in value represented in a table. The amount in the text of the regulation was correct. The table was changed to correspond with the text.

Regulation 28-35-181a was changed to clarify a reference to another part of the regulations. The reference was to the radiation safety committee.

Regulation 28-35-181e was revoked to reflect outdated uses of radioactive materials as required to maintain compatibility with the NRC.

Regulation 28-35-181j was changed to add requirements for the element Radium as required to maintain compatibility with the NRC.

Regulation 28-35-181m was changed to add the positron emission tomography (PET) facility and update the definition of authorized nuclear pharmacist to maintain compatibility with the NRC.

Regulation 28-35-181o was changed to add the word transmission as required to maintain compatibility with the NRC.

Regulation 28-35-192b was changed to add criteria for exemptions for manufacturers, processors or producers as required to maintain compatibility with the NRC.

Regulation 28-35-192c was changed to remove exemptions for certain items that are no longer manufactured as required to maintain compatibility with the NRC.

Regulation 28-35-192d was revoked to remove references to discontinued practices as required to maintain compatibility with the NRC.

Regulation 28-35-192e was changed to add a requirement for license to manufacture, process or produce gas and aerosol detectors containing radioactive material as required to maintain compatibility with the NRC.

Regulation 28-35-192g was changed to add a clarifying statement about the aggregation of radioactive material sources to exceed exempt quantities as required to maintain compatibility with the NRC.

Regulation 28-35-194a was changed to require a specific license with the department if activities are performed within the state in excess of 180 days in a calendar year.

PART 4: STANDARDS FOR PROTECTION AGAINST RADIATION

Amended regulation: K.A.R. 28-35-212a, 28-35-216a, 28-35-231c

New regulation: K.A.R. 28-35-225b

Regulation 28-35-212a was changed to add clarification to calculation methods for determining external exposure as required to maintain compatibility with the NRC.

Regulation 28-35-216a was changed to require radioactive sources in storage to be tested for leakage at least every 10 years.

Regulation 28-35-225b was added to adopt by reference the NRC regulation related to disposal of certain radioactive material as required to maintain compatibility with the NRC.

Regulation 28-35-231c was changed to update the dates for the adoption by reference to maintain compatibility with the NRC.

PART 5: USE OF X-RAYS IN THE HEALING ARTS

Amended Regulation:
K.A.R 28-35-242

Regulation 28-35-242 was changed to clarify the description of who can order X-rays as requested by the Board of Healing Arts.

PART 6: USE OF SEALED RADIOACTIVE SOURCES IN THE HEALING ARTS

Amended Regulation:
K.A.R 28-35-264

Regulation 28-35-264 was changed to update the adoption by reference date as required to maintain compatibility with the NRC.

PART 10: NOTICE, INSTRUCTIONS AND REPORTS TO WORKERS; INSPECTIONS

Amended Regulation:
K.A.R. 28-35-334

Regulation 28-35-334 was changed to add additional requirements for providing dose information to individual workers as required to maintain compatibility with the NRC.

PART 11: WIRELINE AND SUBSURFACE TRACER STUDIES

Amended Regulation:
K.A.R 28-35-346

Regulation 28-35-346 was changed to correct minor errors in the text.

PART 13: CONTINGENCY PLANNING FOR RESPONSE TO RADIOACTIVE MATERIAL EMERGENCIES

Amended Regulation:

K.A.R. 28-35-411

Regulation 28-35-411 was changed to add requirements for the element Radium as required to maintain compatibility with the NRC.

ENVIRONMENTAL AND ECONOMIC IMPACT:

I. Environmental Benefit Statement

1) Need for proposed amendments and environmental benefit likely to accrue.

a) Need

The amendments, revocations and new regulations included in the package fall into two broad categories. The first category encompasses regulations that need to be updated to maintain compatibility with the corresponding Nuclear Regulatory Commission(NRC) regulation. The second category includes regulations that are being updated to meet internal or external stakeholder requests to clarify or improve the structure of the existing regulations.

b) Environmental benefit

The purpose of the regulations is to assure that all whom may operate and own radioactive materials or radiation devices, are current and up to date with the current best practices and consistent with other states' safety regulations, with the overall purpose of ensuring the maximum protection of the environment, public health and the maximum safety to all persons at, or in the vicinity of, the place of use, of radiation.

2) When applicable, a summary of the research indicating the level of risk to the public health or the environment being removed or controlled by the proposed rules and regulations or amendment.

The risks associated with the radiation exposure to be controlled utilizing these revisions have already been determined within the federal rule-making process and through a consensus process of state radiation control programs.

3) If specific contaminants are to be controlled by the amendment, a description indicating the level at which the contaminants are considered harmful according to current available research.

As noted above, these determinations have been made at the federal level; the state rules with respect to contaminants are no more stringent than the federal rules.

II. Economic Impact Statement

1) Are the amendments mandated by federal law as a requirement for participating in or implementing a federally subsidized or assisted

program?

The following applies to Parts 1, 3, 4, 6, 10, 11 and 13 with respect to radioactive material:

Yes, under the NRC-Kansas delegation agreements, the state of Kansas is required to adopt state-enforceable rules compatible with federal rules in order to gain the authority for the administration and enforcement of these standards in the state.

The following applies to Part 5, with respect to use of X-rays in the Healing Arts:

No, however, the largest source of radiation exposure from man-made sources is from radiation producing devices. These regulations fill a gap in the federal regulations with respect protecting the public and environment from the harmful effects of radiation from radiation producing devices while encouraging the constructive use of radiation.

2) Do the proposed amendments exceed the requirements of applicable federal law?

No.

3) Description of costs to agencies, to the general public and to persons who are affected by, or are subject to, the regulations:

a) Capital and annual costs of compliance with the proposed amendments and the persons who will bear those costs.

Part 1- No economic impact, this change updates the adoption by reference to the current federal regulation.

Part 3 Most of the changes in this part are minor in nature and will have no impact on the costs to licensees. K.A.R. 28-35-180b includes an increase in financial assurance amount necessary to ensure adequate funding for decommissioning. Currently no licensees utilize the financial assurance option which will be affected by this change. K.A.R. 28-35-194a limits the amount of time a licensee may be in the state under reciprocity to 180 days. This is not expected to impact licensees since to date none have utilized reciprocity for greater than 180 days.

Part 4 The changes in this part ensure compatibility with federal regulations and do not have an economic impact on existing licensees. K.A.R. 28-35-216a limits the time a sealed source may be in storage without a leak test to 10 years. This will result in a minor cost impact at 10 year intervals.

Part 5 The changes in this part clarify who may order x-rays without changing the original intent.

Part 6 No economic impact, this change updates the adoption by reference to the current federal regulation.

Part 10 None, the changes clarify the intent of the existing regulations

Part 11 None K.A.R. 28-35-346 was changed to correct minor errors in the text.

Part 13 None. These regulations are not applicable to any current licensees or registrants.

b) Initial and annual costs of implementing and enforcing the proposed amendments, including the estimated amount of paperwork, and the state agencies, other governmental agencies or other persons or entities who will bear the costs.

There should be no increase in costs for the department or other state agencies as a result of the proposed amendments.

c) Costs which would likely accrue if the proposed regulations are not adopted, the persons who will bear the costs and those who will be affected by the failure to adopt the regulations.

If failure to adopt the regulations results in the Nuclear Regulatory Commission (NRC) reasserting its authority over the control of radioactive sources in Kansas, the state radiation control program could continue to have responsibility for radioactive materials which are not NRC regulated and x-ray devices. The program would be doing the same work with a smaller group of licensees. The radioactive materials licensees would find their costs increased on an annual basis by a factor of two in terms of license, inspection and annual fees charged by NRC. The current Kansas fees are included in a single annual fee paid by each licensee or registrant.

d) A detailed statement of the data and methodology used in estimating the costs used in the statement.

Costs were estimated using comparisons of NRC versus Kansas license and registration fees as well as data provided by NRC regulatory analyses.

e) Description of any less costly or less intrusive methods that were considered by the agency and why such methods were rejected in favor of the proposed regulations.

There are no alternative methods of implementing the federal requirements that would be less costly or less intrusive.

f) Consultation with League of Kansas Municipalities, Kansas Association of Counties, and Kansas Association of School Boards.

The department does not anticipate that the proposed amendments will have a fiscal impact on the constituencies of these organizations. When the proposed

amendments are issued for public comment, a copy of the Regulatory Impact Statement will be sent to each of the organizations.